EXHIBIT 61

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

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Dr. Bell said that learning of an event such as this outbreak presents an opportunity to ensure that no one else is exposed. Additionally, the event raises questions regarding what to do about the people who have been exposed. The denominator is substantial. The number of procedures performed using these devices that are essential for lifesaving surgeries is high. Many procedures using these devices occur without negative outcomes. Detection of this cluster is due to clinicians' awareness and thoughtfulness. This situation is not a massive crisis, but it is an indication that much is undetected in the patient care environment.

The response to this outbreak is an effective example of a state health department and a facility reacting appropriately and getting appropriate partners involved quickly. Taking the affected machines out of circulation immediately was a good strategy. There is not a straightforward answer regarding how to move forward with these machines

Outreach to potentially involved patients and others has taken place in a short amount of time. These efforts began with the usual groups of healthcare epidemiologists and infection control colleagues to ensure that there is awareness of the issue throughout the hospital. There is also an immediate need to talk to individuals who manage operating theaters to make them aware of the situation. Materials management and the hierarchy of facilities management are also involved. Groups that have experience in what happens in an operating theater, such as the Association of periOperative Registered Nurses (AORN) and profusionist groups have been involved. Outreach has also taken place with other clinical colleagues. The devices are used not only for heart surgeries, but also in other procedures such as liver transplants. This indolent infection presents with non-specificity. It can present as a suppurative surgical wound, or it can also be a deeper infection with non-specific symptoms such as fever and failure to thrive. There are significant in correct diagnosis. Outreach can mitigate the delays, as clinicians with patients who might have been exposed are thinking about NTM as a possibility.

CDC also convened professional groups of individuals who care for NTM-type patients to ask whether there are simple and effective measures to offer patients who might have been exposed. The short answer is that there are not, partly because antimicrobial choices change dramatically based on the species. Additionally, if the infection is recognized appropriately, the treatment is generally manageable and successful. The benefit of post-exposure prophylaxis is therefore unproven and may have adverse consequences (including antibiotic resistance emergence).

The heater-cooler unit appears to be harmless from an infection perspective, but the water overflow bottle is likely rarely, if ever, sanitized and is situated in front of a fan. Nothing that blows air should be in an operating theater, if possible. That risk assessment approach is not built into these devices. The Swiss facility moved the machine outside the operating theater on the other side of a wall. There are concerns about trip hazards from longer tubes and less effective operation because of the dissipation of heat, but it is important not to blow air in the operating theater. In looking inside the machine, it is clear that a reservoir of warm water in a steel container in a chilled operating theater will have condensation that will drip. The insulation layered inside the machine is a non-cleanable foam. The situation is perfect for growing all manner of organisms, not just NTMs. NTMs happen to be durable and noticeable enough to be identified as a surgical case cluster, but there could be other organisms as well. There could be protection for patients from perioperative prophylaxis, which could mask the other organisms.

This experience regarding devices raises the questions: What are the unintended infectious disease risks related to devices in surgical settings? How cleanable are the devices?

The cleaning and maintenance instructions for the heater-cooler unit focused on the basin and the tube of circulating water. These elements are not likely to be the primary culprit for the organism growth. It is more likely that other factors contribute to the problem. The opening for refilling the reservoir is approximately two inches in diameter, leading to the likelihood that water is likely to spill over the edges. There is non-cleanable insulation within the device. The large cooling fan at the base of the device and louvers on the side of the machine contribute to chaotic dispersal of potentially contaminated air.

More infections have not been observed, probably due to good practices within operating theaters, such as air exchanges. The devices are not likely to be pointed directly toward the operative site. There may be concerns associated with the smaller cooling fan that blows air out of the device because it is closer to tables that may hold sterile equipment.

A systematic review of practices should be engineered to determine these issues. Currently, such a review is not part of anyone's job responsibilities. Materials management follows the manufacturer's instructions for cleaning. The operating room staff, surgeons, and infection control personnel do not perform this kind of risk assessment. It is likely that another device will be discovered to be problematic. Consideration must be given to what must be done in advance for the next series of devices. Also important to contemplate is how industry should be informed about expectations as devices are being designed, not from a regulatory perspective, but from a microbiologic, patient safety perspective. An approach that provides design considerations for patient safety may merge well with the regulatory aspects of medical device development.

Discussion Points

Dr. Cardo thanked Dr. Diekema and Dr. Yokoe for their rapid response in helping to identify experts to address questions regarding prophylaxis. She thanked the HICPAC liaison representatives who were also responsive to the calls to expand the partners who have contributed to this work.

Dr. Bell added that the American Hospital Association (AHA) helped CDC make connections. Laboratory staff from CDC visited the hospital sites and were able to collect samples to make a direct connection between the devices and the infections in patients.

Regarding the recommendation on using sterile water, HICPAC asked about consideration of treating the water with chlorine or otherwise.

Dr. Perz replied that the topic of treating water is challenging due to the potential for corrosive effects and various incompatibilities. FDA is working with manufacturers to bring more clarity to the question. The current, generic recommendation is to place a .22 micron filter on the water source that is used to fill the unit.

Dr. Bell was skeptical about sterilizing the water as a solution to the problem. Sterile water may go into the basin, but the basin is open to the environment and there is persistent wetness within the circuit, so there will be organisms. Sterilization will also not answer the question of condensate pooling in the device. The problem centers on maintenance of the device and